EXHIBIT L

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-2327
MDL No. 2327

THIS DOCUMENT RELATES TO:

Nancy Hooper, et al. v. Ethicon, Inc., et al.
Case No. 2:12-cv-00493

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

EXPERT REPORT OF DR. VLADIMIR IAKOVLEV

My general opinions on the Gynemesh mesh product can be found in my general Rule 26 report for all Ethicon products in this MDL, and is incorporated by reference herein.

CLINICO-PATHOLOGICAL CORRELATION OF COMPLICATIONS EXPERIENCED BY MRS. NANCY HOOPER

This section of the report provides a case-specific assessment. The complete report includes a separately provided general part and the provided herein case-specific section. My opinions are based on both, the case specific assessment and the knowledge and experience I gained through the assessment of other implantable transvaginal devices, including those manufactured by Ethicon.

Summary of clinical records

I reviewed clinical records of Mrs. Nancy Hooper. The records were screened focusing on:

- Events and symptoms with temporal relationship to mesh placement, alteration, or excision
- Symptoms, procedures and results of investigations that potentially could be Anatomically and pathophysiologically related to the urogenital area and the mesh
- Alternative medical conditions, procedures and results of investigations that potentially could cause or explain symptoms and complications attributed to the mesh and related procedures in error.

Background medical history:

Bilateral rib fractures, ischemic colitis, cervical degenerative disc disease, osteoporosis, arthralgias with positive rheumatoid factor (without inflammatory arthropathy), trochanteric bursitis.

Background surgical history:

Hysterectomy at age 40

Urogynecological history:

10/28/2010. Chattanooga Family Practice. Dr. Close. Mrs. Hooper presents with gross hematuria. Associated symptoms include flank pain and dysuria. No prior work-up for hematuria has been done. Of note, medical history is negative for kidney stones and pyelonephritis.

12/14/2010. Parkridge Medical Center. Dr. Ashcraft. **Robotic assisted sacral colpopexy with Gynecare Gynemesh.** There were no intra/perioperative complications.

01/24/2011. Dr. Cockerham. The patient is a 54-year-old female with I day history of abdominal pain, sharp, cramping in bilateral lower quadrants, and started with nausea and vomiting late yesterday.

01/24/2011. Parkridge East Hospital. Dr. Cockerham. **Diagnostic laparoscopy, adhesionlysis, removal of foreign body**. The patient is a very pleasant 54-year-old white female who 6 weeks ago underwent a laparoscopic colpopexy by Dr. Ashcraft. She subsequently presented 2 days ago with significant abdominal pain and nausea and a CT consistent with a small bowel obstruction. She was brought to the operating table for a diagnostic laparoscopy, possible small bowel resection.

There was some inflammation noted at the level of the pelvis around the suture. We then ran the small bowel and noted area of induration on the antimesenteric border of the proximal ileum. We visualized this. There was no evidence of perforation. There was certainly fibrous adhesion and this was felt to be the area of obstruction.

There was an exposed suture from the colpopexy and this was sharply excised and removed. This left no exposed foreign bodies. We then placed a piece of INTERCEED mesh over the previous excision site.

02/08/2011. Chattanooga Women's Specialists. Dr. Cockerham. Ms. Hooper is here for follow-up after a small bowel obstruction at East Ridge Hospital. She is feeling some better. She had some significant left-sided abdominal pain yesterday and then she said this was followed by a large bowel movement. She is worried she might have some sort of a stricture related to her previous bout of ischemic colitis.

03/08/2011. Dr. Cockerham. Ms. Hooper is here for follow-up. She states she is still having severe lower pelvic pain, having difficulty with eating, and having painful bowel movements. She is still concerned that she has not had her complete improvement in symptoms after her surgery.

04/12/2011. Chattanooga Family Practice. Dr. Close. Patient to be evaluated for dysuria. This began within the last 1 to 2 months. Associated symptoms include abdominal pain, flank pain, hesitancy, urgency and urinary frequency. She denies associated chills. Mrs. Hooper states that she had multiple prior episodes of similar discomfort. Follow up of female pelvic pain. The condition since last visit is about the same. Just no improvement since her surgery; feels a great deal of pressure in lower abdomen/vaginal area; uncomfortable; would like a 2nd opinion.

04/19/2011. Dr. Cockerham. Ms. Hooper is here for a follow-up. She apparently had severe pain over the weekend that continued. Yesterday it became somewhat better. She states she is having quite a bit of dysuria and lower abdominal pain as well. She has had no large volume emesis. Her bowel movements have not changes as far as I can tell per her report.
IMPRESSION: At this point, Ms. Hooper still states she has had significant discomfort since her pelvic sling. She has been referred to a second gynecologist by Dr. Richard Moody for evaluation. She asked me about removing the sling and I have deferred this to gynecology. Otherwise there is no evidence of bowel obstruction, at least, per her CT report. We will treat her

presumed urinary tract infection with some antibiotics and see if this will give her some symptomatic relief.

04/25/2011. Dr. Furr. Referred visit, history summarized: the patient states that she had a robotic sacrocolpopexy performed in December 14, 2010 at Park ridge Hospital by Dr. Delman Ashcraft for symptomatic pelvic organ prolapse. The patient states that she went home the next day and always had a lot of pain after the surgery then developed persistent vomiting and went to the Emergency Room at East Ridge Hospital on December 31, 2010 and had an NG-tube placed and she says they put Gal YTELY down this until she had a bowel movement. When she had a bowel movement she was sent home. Unfortunately, she reports that she did not get any better and continued to have the extreme abdominal pain, swelling, and then nausea and vomiting again and she returned to the Emergency Room at East Ridge Hospital on January 24, 2011 where she was evaluated by Dr. Todd Cockerham, a local general surgeon, who performed diagnostic laparoscopy and found that she had a loop of small bowel reportedly adhered to the mesh and she brings pictures of this with her. I have not seen the operative reports. In addition, the patient now complains of dyspareunia and has lost significant amount of weight because she is afraid to eat because she has pain with her bowel movements and abdominal pain if her abdomen gets too full. She also says that she continues to have all of the urinary symptoms that she had prior to the surgery.

Incidentally, she did not have a urodynamic study performed prior to her procedure and claims that she was not given any of the risk associated with placement of the foreign body mesh material. She states that she is unable to have intercourse with her husband because it is too painful. She has what

sounds like urge incontinence symptoms, which were the same as before surgery and she still has leakage of urine with Valsalva. She says that she did not have any of the dyspareunia prior to the surgery

Assessment:

Ms. Hooper is a very pleasant 54-year-old Caucasian gravida 1 para 1-0-0-1 who presents today at the kind request of her internist Dr. Richard Moody for gynecologic consultation regarding the history of abdominopelvic pain, dyspareunia, and voiding function status post

robotic sacrocolpopexy on December 14, 2010. I have reviewed the photographs from her surgical procedure with Dr. Cockerham, which revealed some information of the small bowel apparently where it was attached to the mesh and also looks like she may have had some adhesion of the right tube and ovary as well. There is no any clear picture provided of the area from the sacrum to the vaginal apex to determine whether or not there was closure of the peritoneum over the mesh. The patient continues to have persistent abdominopelvic pain. She has abdominal pain and painful bowel movements and therefore has avoided eating any significant amount of food. She also complains of continued, possibly worsened voiding dysfunctions since the procedure and she is currently unable to have any coitus with her husband secondary to dyspareunia. She did have some tenderness of the urogenital diaphragm and posterior vaginal wall on examination today. However, there was no extravasation of the mesh material through the vaginal mucosa.

At the current time she does have an excellent result from the sacrocolpopexy from an anatomic standpoint with no evidence of anterior or posterior compartment defects and adequate suspension of the vaginal apex. Therefore1 at this time I would not recommend any surgical procedure to take down the\ sacrocolpopexy graft. However she may eventually need a repeat diagnostic laparoscopy to re-evaluate for adhesions as she does give some symptoms of this including a pulling sensation on her bladder when she voids.

07/15/2011. Erlanger Health System. The patient was evaluated in the office and did not have any leakage of urine with Valsalva maneuver. A methodical vaginal examination was performed, and she did not have any evidence of mesh extrusion or exposure. She was then asked to perform sustained Kegel contraction, and she had mild trigger points of the urogenital diaphragm. On bimanual examination, no foreign body material was palpated; however, she had significant tenderness to the anterior vaginal wall and to a lesser degree the posterior vaginal wall. She had good anatomic results from her sacral colpopexy. The patient was subsequently started on an aggressive re-estrogenization of the vaginal tissues with Estrace vaginal cream and was referred to Melissa Kubic at Siskin Physical Therapy for evaluation and treatment with plans to possibly start her on Elavil and eventually obtain a urodynamic study. The patient was seen back in the office on 6/7/2011, and she had her urodynamic study which revealed no evidence of stress

incontinence at 302 mL, and no evidence of detrusor overactivity during bladder filing with provocation. However, she had significant bladder pain and/or sensory urgency during bladder filling.

She did not notice any significant change in her bladder urgency, and therefore, the plan at this time will be to evaluate her for interstitial cystitis or possibly foreign body erosion into the bladder.

IMPRESSION: She has also subsequently had significant vaginal pain voiding dysfunction and dysuria that is similar to or worse than prior to her surgery. She has shown some improvement with re-estrogenation of the vaginal tissues and physical therapy. However, she continues to have the urinary

frequency which has not responded well to Vesicare, and she also continues to have some dysuria and bladder-type pain consistent with possible painful bladder syndrome or interstitial cystitis.

Therefore, the plan at this time will be to admit her to Day Surgery at Erlanger Hospital on 7/15/2011 for cystoscopy with hydrodistention.

07/15/2011. Dr. Furr. Cystourethroscopy with hydrodistention

FINDINGS: At time of surgery: She had petechial hemorrhages in all 4 quadrants of the bladder, consistent with interstitial cystitis. There were no foreign bodies in the bladder, and both ureteral orifices were jetting clear yellow urine. There were no defects of the urethra.

12/10/2012. Dr. House. Urodynamics impression was of urge incontinence.

01/22/ 13. Parkridge East Hospital. Laparoscopic excision of foreign body (polypropylene mesh from prior sacral colpopexy), lysis of adhesions, laparoscopic right salpingo-oophorectomy, right ureterolysis, cystoscopy with stent placement and removal on the right side, laparoscopic left salpingectomy, resuspension of the vaginal apex to the right mid uterosacral ligament, repair of incidental cystotomy.

INDICATIONS FOR PROCEDURE: The patient is a 56-year-old Caucasian, gravida 1, para 1, who had robot-assisted sacral colpopexy back in December 2011. Ever since procedure, she has

had worsening pelvic pain and dyspareunia in addition to small bowel obstruction and removal of the small bowel from the sacra: colpopexy mesh. She in the interim has been diagnosed with interstitial cystitis and overactive bladder and she is undergoing treatment for this as well as pelvic floor physical therapy. Her pain and her urinary symptoms have improved; however, she continues to have relatively severe dyspareun1a and pelvic pain.

FINDINGS AT THE TIME OF SURGERY: Evidence of prior sacra1 colpopexy with the vaginal apex under significant tension. The right tube and ovary were densely adhesed to the long arm of the sacral colpopexy mesh. The ureter was not clearly visible secondary to the adhesions of the right tube and ovary and the right pelvic sidewall. There were adhesions of the left rectosigmoid colon to the pelvic brim. The ovaries did not compare completely atrophic. The left fallopian tube was normal. There was excellent resuspension of the vaginal apex to the right mid uterosacral ligament at the end of the procedure. Approximately 1.5-2 cm incidental cystotomy was made during the dissection of the bladder off of the mesh graft. There were no colpotomies. There was no injury to the bowel or other structures. The mesh was removed from approximately m1dway up the long arm of the mesh and the anterior and posterior attachments were removed in its entirety. At the time of cystourethroscopy, both ureters were jetting indigo carmine stained urine and ·there was evidence of or repair.

Pathology:

Southern Pathology Associates

Parkridge East Hospital

2013-000-563

Diagnosis:

A. Right tube/ovary:

Atrophic-appearing ovary with several small benign surface inclusion cysts.

Fallopian tube with small benign paratubal cysts.

Tubo-ovarian adhesions.

B. Left fallopian tube:

Fallopian tube with small benign paratubal cysts.

C. Sacrocolpopexy mesh:

Surgical mesh with adherent reactive fibrous tissue showing mild chronic inflammation and foreign body reaction.

Gross:

A. Received is a container labeled Nancy Hooper, right ovary/tube. A portion of rubbery tan-pink and pink-white tissue 3.4 x 2.8 x 1.3 cm, is focally roughened and mottled red-brown over the surface. The specimen is serially sectioned and submitted as blocks 1-3. (7b/3c)

B. Received is a container labeled Nancy Hooper, left fallopian tube. A fimbriated portion of fallopian tube, 3.6 cm in length averages 0. 7 cm in diameter, is focally roughened over the external surface. Sectioned surfaces are grossly not unusual and representative sections are submitted as block 1. (3b/1 c)

C. Received is a container labeled Nancy Hooper, sacrocolpoplexy mesh. A Y-shaped portion of sacrocolpoplexy mesh is overall 4.9 x 4.7 x 0.3 cm and is partially encapsulated by strands of rubbery tan-pink and red-brown tissue. A representative section of soft tissue is submitted as block 1 and the specimen is returned to risk management to be returned to the "attorney's office".

01/28/2013. Dr. Duke. 5 days ago underwent a laparoscopic removal of sacral colpopexy mesh. She had previously had a small bowel obstruction with her original sacral colpopexy surgery and was admitted to the hospital for a number of days and actually, at that time, had a diagnostic laparoscopy and was found to have mesh eroding into the bowel, which was revised. This past Tuesday, she had surgery to remove any remaining mesh that was continuing to cause dyspareunia.

She did well in the immediate postoperative period, but yesterday started having diffuse abdominal pain as well as feeling warm than cool. She, this morning, wake up and her abdominal pain was even worse, and she had as persistent nausea and vomiting, which she thought was consistent with her previous small bowel obstruction 2 years ago. Due to this, she presented to the ER where a CT was performed and diagnosis of small bowel obstruction was made.

08/09/2013. Parkridge East Hospital. CT scan. Abnormal thickening of the wall of the descending colon. This may be due to inflammatory, infectious or ischemic colitis. No other acute findings are visible.

11 /11 /2013. Chattanooga Family Practice. Dr. Close. Mrs. Hooper presents with UTI. This began within the last 1 to 2 weeks. Initially improved with Bactrim from GYN's office, but now symptoms are back. Associated symptoms include flank pain, nausea and urgency. She denies associated fever or vomiting. Mrs. Hooper states that she had multiple prior episodes of similar discomfort, which were diagnosed as interstitial cystitis. Treatments tried thus far include increased fluid intake.

11/17/13. Parkridge East Hospital. This is a 57-year-old white female who came to the emergency department for evaluation of nausea, vomiting and abdominal pain in the left lower quadrant. The abdominal pain, nausea, and vomiting is now better. She has not had bowel movements for about four days. CT scan of the abdomen does show that the patient has got large amount of stools in the left lower quadrant.

02/03/2014. Nancy presents today for a routine follow up. She had ischemic colitis in August and then in December had a bowel obstruction. She was admitted to the hospital for both of these episodes. The bowel obstruction did not require surgery. Dr. Shah has performed colonoscopy and he told her that her colon was "very twisted" and he had to use a pediatric colonoscope.
On a positive note, she does report that she has resumed intercourse and it was "pleasant." She did not experience any pain. This is excellent for her. She has not been using the Estrace cream and I strongly encouraged this.

12/31/2013. Chattanooga Family Practice. Dr. Close. Dysuria details; this began within the last 4 days. Associated symptoms include abdominal pain (constant, pressure like), hesitancy, urgency and urinary frequency.

09/03/2014. Chattanooga Family Practice. Dr. Close. In regard to the low back pain, the discomfort is most prominent in the lower thoracic spine and in the upper, mid, and lower lumbar spine. She characterizes it as constant and moderate in intensity. She states that the current episode of pain started 7 days ago. She does not recall any precipitating event or injury. Associated symptoms include weakness of the upper leg. She denies incontinence. She notes

some pain relief with heat. Medical history is significant for had mesh placed as part of bladder tack, later removed, has had problem off & on since. She denies history of back surgery, current back-related disability income or obesity. Dx with abdominal pain; this is located primarily in the pelvis. It does not radiate. It began several weeks ago. Aggravating factors include eating. The pain is relieved with not eating. Associated symptoms include nausea and vomiting. She denies melena, red bloody stools or sweats.

07/31/2015. McMinnville Orthopaedic Clinic. On exam, she has diffuse tenderness on her low back. Neurologically, she seems intact although she is developing atrophy in the thigh and calf on the left. I have again requested an MRI scan for the lumbar spine. Since having the pelvic mesh, her condition seems to have deteriorated and I will therefore will get an MRI scan of the pelvis as well and a bone scan to check for any signs of infection.

Pathological findings

I received:

1. 3 H&E stained slides prepared at the Parkridge Hospital and labeled:
   N HOOPER
   13-563 C1
   1 SPA RC-1-2
1. Dried tissue in a container labeled with the patient's name and:

   BD: 08/05/56

   Furry, Rupert Scott

   01/15/13

   Parkridge East Hospital

   1. Sacropexy mesh

   Pathology label:

   PC: SS-13-563

   01/23/13

The corresponding pathology report reads as:

Parkridge East Hospital

2013-000-563

Diagnosis:

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Fallopian tube with small benign paratubal cysts.

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B. Received is a container labeled Nancy Hooper, left fallopian tube. A fimbriated portion of fallopian tube, 3.6 cm in length averages 0. 7 cm in diameter, is focally roughened over the external surface. Sectioned surfaces are grossly not unusual and representative sections are submitted as block 1. (3b/1 c)

C. Received is a container labeled Nancy Hooper, sacrocolpopexy mesh. A Y-shaped portion of sacrocolpopexy mesh is overall 4.9 x 4.7 x 0.3 cm and is partially encapsulated by strands of rubbery tan-pink and red-brown tissue. A representative section of soft tissue is submitted as block 1 and the specimen is returned to risk management to be returned to the "attorney's office".

Microscopic description:

1. Sections of the original slides prepared at the Parkridge Hospital showed a portion of excised mesh within maturing granulation tissue (loose inflamed scar tissue) (Figure NH1). The tissue had moderately dense chronic non-specific inflammation. There were also fragments of tissue from the peritoneal (abdominal) cavity, reactive serosal surface and/or parts of the fallopian tube (Figures NH2&3). These fragments were in keeping

with the intraoperative description of mesh exposure through peritoneum and involvement of the right fallopian tube.

2. The material received in the container consisted of mesh and incorporating it dried tissue (Figure NH4). The material was divided in half, ½ was retained by the defense expert and the other ½ was processed as a routine consultation case of St. Michael's hospital. Sections of the specimen portion processed at St. Michael's hospital showed tissue affected by drying. There was monofilament mesh embedded in scar tissue (Figure NH5). Some parts of the mesh were incorporated by the tissue in folded configuration. There was a cellular zone around the mesh fibers consistent with foreign body type inflammatory reaction (Figure NH6). One part of the mesh had density of inflammation similar to the fragment seen in the earlier processed part of the specimen (Figure NH7).

Polypropylene degradation:

At high magnification the mesh fibers in both, slides prepared at the Parkridge and St. Michael's hospitals showed an outer layer of degraded polypropylene (Figures NH8-10). The degraded material absorbed histological dyes and stained purple in H&E stained sections while the non-degraded core remained clear. Although altered, the degraded material retained birefringence (brightness in polarized light) of polypropylene. The layer of degraded polypropylene showed cracking and peeling indicating its brittleness.

There were no pathological findings of natural, non-mesh related diseases or another foreign body in either part of the specimen (slides prepared at the Parkridge and St. Michael's hospitals)

Clinico-pathological correlation

Mrs. Hooper had sacral colpopexy with Gynecare Gynemesh in December 2010. Six weeks later she presented with bowel obstruction and was taken to OR. The small bowel was found to be affected by adhesions in the pelvis, at the area described as "suture" at the time. Later in 2011 Ms. Hooper continued to have persistent abdominopelvic pain and painful bowel

movements and therefore avoided eating any significant amount of food. She had continued, or had worsened voiding dysfunctions. She also reported dyspareunia. On examination there was tenderness of the urogenital diaphragm and anterior (less tenderness of posterior) vaginal wall, while there was no mucosal mesh erosion. She was diagnosed with interstitial cystitis and overactive bladder. Conservative treatment gave only partial effect and Ms. Hooper was taken to OR again in January 2013, for mesh excision and lysis of adhesions. The right tube and ovary were densely adhered to the long arm of the sacral colpopexy mesh. The ureter was not clearly visible secondary to the adhesions of the right tube and ovary and the right pelvic sidewall. There were adhesions of the left rectosigmoid colon to the pelvic brim. At the original pathology lab adhesions were described at the right tube and ovary.

Overall, clinical investigations and trials of conservative therapy resulted in the decision to excised mesh to treat the developed complications. When the mesh was removed, there was no evidence of malignancy or another natural disease in the specimen. Therefore, both clinical and morphological findings narrowed the differential diagnosis of specific symptoms to the mesh:

Peritoneal adhesions:

Clinically, both the small bowel and the right tube & ovary were found to be adherent to the mesh. This caused partial bowel obstruction within 6 weeks after the mesh surgery.

When the mesh was removed there was no other foreign body or a non-mesh related disease to cause the adhesions. A part of the mesh was associated with a higher than usual for the postoperative timing chronic inflammation. There were also portions of peritoneal surface and/or fallopian tubes. Adhesions of the right tube and ovary were described by the original pathological examination. These findings were in support with the intraoperative description of the right tube adherent to the mesh where the area was associated with the peritoneal adhesions.

Peritoneal adhesions are a recognized and likely underreported complication of sacropexy operations with the mesh.[1] Negative effect of polypropylene mesh exposure to the bowel has been well recognized in hernia surgery where new designs employ a barrier layer to prevent bowel adhesions. Unfortunately, even exptraperitoneal mesh can migrate and cause peritoneal adhesions.[2-7]

Based on my knowledge and experience, published literature and my own research in the field of implantable meshes, my review of the clinical records of Mrs. Hooper and examination of the specimen described above, it is my opinion to a reasonable degree of medical certainty that the mesh and associated tissue changes caused intraabdominal adhesions to the mesh for Mrs. Hooper. It is further my opinion to a reasonable degree of medical certainty that the residual mesh, tissue damage and scarring caused by the mesh and the excision surgery continue to pose a risk adhesions.

1. Nygaard IE, McCreery R, Brubaker L, Connolly A, Cundiff G, Weber AM, Zyczynski H; Pelvic Floor Disorders Network. Abdominal sacrocolpopexy: a comprehensive review. Obstet Gynecol. 2004;104(4):805-23.
2. Barnes MG. Irritable bowel syndrome: a "mesh" of a situation. J Am Board Fam Med. 2012;25(1):120-3.
3. Chen MJ, Tian YF. Intraperitoneal migration of a mesh plug with a small intestinal perforation: report of a case. Surg Today. 2010;40(6):566-8.
4. Lo DJ1, Bilimoria KY, Pugh CM. Bowel complications after prolene hernia system (PHS) repair: a case report and review of the literature. Hernia. 2008;12(4):437-40.
5. Ojo P1, Abenthroth A, Fiedler P, Yavorek G. Migrating mesh mimicking colonic malignancy. Am Surg. 2006;72(12):1210-1.
6. Ferrone R, Scarone PC, Natalini G. Late complication of open inguinal hernia repair: small bowel obstruction caused by intraperitoneal mesh migration. Hernia. 2003;7(3):161-2.
7. Chuback JA, Singh RS, Sills C, Dick LS. Small bowel obstruction resulting from mesh plug migration after open inguinal hernia repair. Surgery. 2000;127(4):475-6.

Pain:

Abdominal and pelvic pain was repeatedly described in the records. In part, the abdominal component of the pain was related to the bowel adhesions. Ms. Hooper tried to control this pain avoiding larger meals. Bowel adhesions also triggered an emergency surgery 6 weeks after the mesh placement. Relationship of the adhesions to the mesh is discussed above.

The pelvic component of the pain was likely partially related to the adhesions, but a part of it was elicited during the physical examination when vaginal walls were found to be tender. As described, the excised specimen showed changes only related to the mesh and no other foreign body or a natural disease was detected. The mesh triggered scarring and inflammation. Physiologically, scar tissue contracts during its maturation stage. Scar tissue around and within the mesh also contracts which leads to mesh tightening and stiffening. It also leads to distortion of the attached tissues.

Another factor of importance was mesh related inflammation. Inflammation has a dual significance for the pathological changes in the tissues. It lowers the threshold for pain sensation and acts as a source of tissue damage and scarring. As we all experience in our body, a light touch of an inflamed area can be felt as pain. It is also well established that chronic inflammation causes fibrosis/scarring.

Based on my knowledge and experience, published literature and my own research in the field of implantable meshes, my review of the clinical records of Ms. Hooper and examination of the specimen described above, it is my opinion to a reasonable degree of medical certainty that the mesh and the associated tissue changes caused vaginal/pelvic pain symptoms experienced by Ms. Hooper. It is further my opinion to a reasonable degree of medical certainty that the residual parts of the mesh which were not removed during the excision surgery, as well as the tissue damage and scarring caused by the mesh and the excision surgery continue to pose a risk for pelvic/vaginal pain.

Dyspareunia:

Dyspareunia was reported in the medical records. Generally, the symptoms of dyspareunia are caused by additional stressors, direct physical or stimulated (muscle contraction) acting on vulnerable tissues. The discussed above mechanisms for chronic pain made the tissues vulnerable during intercourse. The mechanical stress of intercourse was being applied to the tissue already at risk for pain through several mechanisms. These mechanisms included inflammation, scarring with mesh contraction and tissue distortion, and pelvic adhesions. Additionally, during intercourse the sensitive vaginal mucosa was at risk for compression against an irregular stiffened mesh-scar plate.

Based on my knowledge and experience, my research in the field of implantable meshes, my review of the clinical records of Mrs. Hooper and examination of the specimen described above, it is my opinion to a reasonable degree of medical certainty that the mesh and the associated tissue changes caused dyspareunia for Mrs. Hooper. It is further my opinion to a reasonable degree of medical certainty that the residual parts of the mesh device which were not removed during the excision, and scarring caused by the mesh and the excision surgery continue to pose a risk for dyspareunia.

Polypropylene degradation:

The mesh fibers showed an outer layer of degraded polypropylene. The degraded material retained birefringence (light polarization properties) of polypropylene. However, unlike the non-degraded core of the mesh fibers, the degraded material absorbed histological dyes. The molecules of histological dyes were trapped in the nanopores/nanocavities formed due to degradation.

The degraded polypropylene showed cracking which is a factor of clinical importance. Cracking indicated brittleness and internal contraction forces. The degraded polypropylene formed a continuous brittle sheath around the mesh filaments contributing to mesh stiffening. Extensive cracking can also provide cavities to harbor bacteria, as is well known in microporous meshes. Additionally, degradation of a substance indicates its breakdown into smaller molecules or/or particles, and, in cases of implanted materials the products of degradation are released into the tissue adding to the complex pathological interactions between the mesh and the human body.

Based on the pathological findings described above; my knowledge, training and experience; my review of the scientific literature and my own research work in the field of implantable devices, it is my opinion that polypropylene of the mesh devices degraded while in the body of Mrs. Hooper.

I reserve the right to supplement this report if new information becomes available. My billing rate is $475 per hour.

Sincerely,

Vladimir Iakovlev, MD, FRCPC, FCAP DATE: January 26, 2016